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ATTORNEY DOCKET NO. APPLICATION NO. FILING DATE FIRST NAMED INVENTOR CONFIRMATION NO. 10/085,639 02/28/2002 Donald J. McMichael KCX-518B (17507B) 5371 **EXAMINER** 06/21/2004 7590 STEPHEN E. BONDURA, ESQ. FOSTER, JIMMY G DORITY & MANNING, P.A. ART UNIT PAPER NUMBER P.O. BOX 1449 GREENVILLE, SC 29602-1449 3728

DATE MAILED: 06/21/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Interview Summary	Application No.	Applicant(s)
	10/085,639	MCMICHAEL ET AL.
	Examiner	Art Unit
	Jimmy G Foster	3728
All participants (applicant, applicant's representative, PTO personnel):		
(1) Jimmy G Foster.	(3)	
(2) <u>Neil P. Pierotti</u> .	(4)	
Date of Interview: <u>17 June 2004</u> .		
Type: a)⊠ Telephonic b)□ Video Conference c)□ Personal [copy given to: 1)□ applicant 2)□ applicant's representative]		
Exhibit shown or demonstration conducted: d)☐ Yes e)☒ No. If Yes, brief description:		
Claim(s) discussed: 1, 3,-21 (draft).		
Identification of prior art discussed: All applied art, but primarily Kalinski and Paikoff(of record).		
Agreement with respect to the claims f)□ was reached. g)⊠ was not reached. h)□ N/A.		
Substance of Interview including description of the general nature of what was agreed to if an agreement was reached, or any other comments: <u>See Continuation Sheet</u> .		
(A fuller description, if necessary, and a copy of the amendments which the examiner agreed would render the claims allowable, if available, must be attached. Also, where no copy of the amendments that would render the claims allowable is available, a summary thereof must be attached.)		
THE FORMAL WRITTEN REPLY TO THE LAST OFFICE ACTION MUST INCLUDE THE SUBSTANCE OF THE INTERVIEW. (See MPEP Section 713.04). If a reply to the last Office action has already been filed, APPLICANT IS GIVEN ONE MONTH FROM THIS INTERVIEW DATE, OR THE MAILING DATE OF THIS INTERVIEW SUMMARY FORM, WHICHEVER IS LATER, TO FILE A STATEMENT OF THE SUBSTANCE OF THE INTERVIEW. See Summary of Record of Interview requirements on reverse side or on attached sheet.		
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	Am	SA.
Examiner Note: You must sign this form unless it is an Attachment to a signed Office action.	Examiner's sig	nature, if required

U.S. Patent and Trademark Office PTOL-413 (Rev. 04-03)

Interview Summary

Paper No. 20040617

Summary of Record of Interview Requirements

Manual of Patent Examining Procedure (MPEP), Section 713.04, Substance of Interview Must be Made of Record

A complete written statement as to the substance of any face-to-face, video conference, or telephone interview with regard to an application must be made of record in the application whether or not an agreement with the examiner was reached at the interview.

Title 37 Code of Federal Regulations (CFR) § 1.133 Interviews Paragraph (b)

In every instance where reconsideration is requested in view of an interview with an examiner, a complete written statement of the reasons presented at the interview as warranting favorable action must be filed by the applicant. An interview does not remove the necessity for reply to Office action as specified in §§ 1.111, 1.135. (35 U.S.C. 132)

37 CFR §1.2 Business to be transacted in writing.

All business with the Patent or Trademark Office should be transacted in writing. The personal attendance of applicants or their attorneys or agents at the Patent and Trademark Office is unnecessary. The action of the Patent and Trademark Office will be based exclusively on the written record in the Office. No attention will be paid to any alleged oral promise, stipulation, or understanding in relation to which there is disagreement or doubt.

The action of the Patent and Trademark Office cannot be based exclusively on the written record in the Office if that record is itself incomplete through the failure to record the substance of interviews.

It is the responsibility of the applicant or the attorney or agent to make the substance of an interview of record in the application file, unless the examiner indicates he or she will do so. It is the examiner's responsibility to see that such a record is made and to correct material inaccuracies which bear directly on the question of patentability.

Examiners must complete an Interview Summary Form for each interview held where a matter of substance has been discussed during the interview by checking the appropriate boxes and filling in the blanks. Discussions regarding only procedural matters, directed solely to restriction requirements for which interview recordation is otherwise provided for in Section 812.01 of the Manual of Patent Examining Procedure, or pointing out typographical errors or unreadable script in Office actions or the like, are excluded from the interview recordation procedures below. Where the substance of an interview is completely recorded in an Examiners Amendment, no separate Interview Summary Record is required.

The Interview Summary Form shall be given an appropriate Paper No., placed in the right hand portion of the file, and listed on the "Contents" section of the file wrapper. In a personal interview, a duplicate of the Form is given to the applicant (or attorney or agent) at the conclusion of the interview. In the case of a telephone or video-conference interview, the copy is mailed to the applicant's correspondence address either with or prior to the next official communication. If additional correspondence from the examiner is not likely before an allowance or if other circumstances dictate, the Form should be mailed promptly after the interview rather than with the next official communication.

The Form provides for recordation of the following information:

- Application Number (Series Code and Serial Number)
- Name of applicant
- Name of examiner
- Date of interview
- Type of interview (telephonic, video-conference, or personal)
- Name of participant(s) (applicant, attorney or agent, examiner, other PTO personnel, etc.)
- An indication whether or not an exhibit was shown or a demonstration conducted
- An identification of the specific prior art discussed
- An indication whether an agreement was reached and if so, a description of the general nature of the agreement (may be by attachment of a copy of amendments or claims agreed as being allowable). Note: Agreement as to allowability is tentative and does not restrict further action by the examiner to the contrary.
- The signature of the examiner who conducted the interview (if Form is not an attachment to a signed Office action)

It is desirable that the examiner orally remind the applicant of his or her obligation to record the substance of the interview of each case. It should be noted, however, that the Interview Summary Form will not normally be considered a complete and proper recordation of the interview unless it includes, or is supplemented by the applicant or the examiner to include, all of the applicable items required below concerning the substance of the interview.

A complete and proper recordation of the substance of any interview should include at least the following applicable items:

- 1) A brief description of the nature of any exhibit shown or any demonstration conducted,
- 2) an identification of the claims discussed.
- 3) an identification of the specific prior art discussed,
- 4) an identification of the principal proposed amendments of a substantive nature discussed, unless these are already described on the Interview Summary Form completed by the Examiner,
- 5) a brief identification of the general thrust of the principal arguments presented to the examiner,

(The identification of arguments need not be lengthy or elaborate. A verbatim or highly detailed description of the arguments is not required. The identification of the arguments is sufficient if the general nature or thrust of the principal arguments made to the examiner can be understood in the context of the application file. Of course, the applicant may desire to emphasize and fully describe those arguments which he or she feels were or might be persuasive to the examiner.)

- 6) a general indication of any other pertinent matters discussed, and
- 7) if appropriate, the general results or outcome of the interview unless already described in the Interview Summary Form completed by the examiner.

Examiners are expected to carefully review the applicant's record of the substance of an interview. If the record is not complete and accurate, the examiner will give the applicant an extendable one month time period to correct the record.

Examiner to Check for Accuracy

If the claims are allowable for other reasons of record, the examiner should send a letter setting forth the examiner's version of the statement attributed to him or her. If the record is complete and accurate, the examiner should place the indication, "Interview Record OK" on the paper recording the substance of the interview along with the date and the examiner's initials.

Continuation of Substance of Interview including description of the general nature of what was agreed to if an agreement was reached, or any other comments: The draft claims included new limitations added to the claims which had not been previously considered by the examiner during search and examination. The examiner felt additional search and examination would be necessary to consider the claim changes. Accordingly, the examiner indicated that if the claims were submitted in a formal amendment, they would not be entered since the last Office action was made final. There was a discussion of various ways the claims could be amended to attempt to distinguish over the applied prior art if Applicants were to decide to file an RCE or a continuation.

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Proposed Claim Amendments for Telephone Interview of June 17, 2004 10/085,639 (our KCX-518B)

(Currently Amended) A surgical kit, comprising:

a tray comprising a plurality of planar surfaces defined therein;

a plurality of article recesses defined in said planar surfaces such that at least one said recess is defined in each of said planar surfaces, each said recess having a shape for receipt of a particular surgical article therein;

said planar surfaces comprising

a first planar surface comprising at least one recess of said recesses disposed therein;

a second planar surface comprising at least one recess of said recesses disposed therein, the second planar surface being <u>vertically</u> offset from the first planar surface; and

a third planar surface comprising at least one recess of said recesses disposed therein, the third planar surface being vertically offset from the first planar surface; and

wherein said first, second, and third planar surfaces are all at least partially outside of the perimeter defined by one another, and wherein said planar surfaces are arranged such that each said planar surface is offset vertically with respect to at least one other said planar surface and said recesses are positioned within said tray such that articles in at least one upper said planar surface must be removed from said tray prior to access being provided to articles in at least one lower said planar surface, said

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articles correspondingly arranged in said tray such that unobstructed access is provided to said articles in their order of use for a particular surgical procedure.

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- 2. (Cancelled)
- 3. (Currently Amended) The surgical kit as in claim 1 further comprising

 A surgical kit, comprising:

a tray comprising a plurality of planar surfaces defined therein:

a plurality of article recesses defined in said planar surfaces such that at least one said recess is defined in each of said planar surfaces, each said recess having a shape for receipt of a particular surgical article therein;

said planar surfaces comprising

a first planar surface comprising at least one of said recesses disposed therein;

a second planar surface comprising at least one of said recesses

disposed therein, the second planar surface being vertically offset from the first planar surface; and

a third planar surface comprising at least one of said recesses disposed
therein, the third planar surface being vertically offset from the first planar surface; and
wherein said recesses are positioned within said tray such that articles in at least
one upper said planar surface must be removed from said tray prior to access being
provided to articles in at least one lower said planar surface, said articles

correspondingly arranged in said tray such that unobstructed access is provided to said articles in their order of use for a particular surgical procedure; and

a removable container adapted to fit at least partially within said tray, said container adapted to rest upon at least a portion of said first planar surface while providing access to at least one said recess defined in said first planar surface and covering at least one said recess in said second planar surface, said container being reclosable and containing at least one accessory article useful in performing the surgical procedure.

- 4. (Original) The surgical kit as in claim 3, further comprising a plurality of said recesses defined in said first planar surface below said container such that said container must be removed from said tray prior to having access to articles contained in said recesses below said tray.
- 5. (Original) The surgical kit as in claim 1, further comprising a cover adapted to be placed over said tray.
- 6. (Original) The surgical kit as in claim 1, further comprising at least one boss extending upwardly from at least one of said planar surfaces, said boss configured for extending through at least a portion of a surgical article.
- 7. (Original) The surgical kit as in claim 6, wherein said boss extends through a handle portion of a snare device.
 - (Previously Presented) A surgical kit, comprising:
 a tray comprising a plurality of planar surfaces defined therein;
- a plurality of article recesses defined in said planar surfaces such that at least one said recess is defined in each of said planar surfaces, each said recess having a shape for receipt of a particular surgical article therein; and

wherein said planar surfaces are arranged such that each said planar surface is offset vertically with respect to at least one other said planar surface and said recesses positioned within said tray such that articles in at least one upper said planar surface must be removed from said tray prior to access being provided to articles in at least one lower said planar surface, said articles correspondingly arranged in said tray such that unobstructed access is provided to said articles in their order of use for a particular surgical procedure;

further comprising at least one boss extending upwardly from at least one of said planar surfaces, said boss configured for extending through at least a portion of a surgical article;

wherein said boss extends through a handle portion of a snare device; and wherein said snare device overlies at least a portion of another said article received in a recess defined below the position of said snare device.

- 9. (Original) The surgical kit as in claim 8, wherein said article in said recess below said snare device comprises a percutaneous gastrostomy tube.
- 10. (Original) The surgical kit as in claim 9, further comprising a coiled guide wire overlying a portion of said percutaneous gastrostomy tube.

11. (Currently Amended) A percutaneous endoscopic gastrostomy (PEG) kit comprising:

a tray, said tray further comprising

a first planar surface comprising at least one recess disposed within the first planar surface,

a second planar surface comprising at least one recess disposed within the second planar surface, the second planar surface being offset from the first planar surface,

a third planar surface comprising at least one recess disposed within the third planar surface, the third planar surface being offset from the first planar surface

a container adapted to fit at least partially fitting within the tray, the container-adapted to rest resting upon at least one of the plurality of planar surfaces while leaving at least one said recess in said planar surface exposed, the container adapted to be reclosable and to retain accessory articles useful in performing a medical procedure; and

a cover adapted to be placed over the tray;

wherein each recess is adapted to hold at least one article useful in performing a medical procedure.

12. (Original) The PEG kit as in claim 11, wherein at least one said recess disposed in said first planar surface is adapted to hold a looped placement wire.

- 13. (Original) The PEG kit as in claim 11, wherein at least one said recess disposed in said second planar surface is adapted to hold at least a portion of a percutaneous endoscopic gastrostomy tube.
- 14. (Original) The PEG kit as in claim 13, wherein said percutaneous endoscopic gastrostomy tube comprises a bumper, said bumper disposed within at least one said recess in said second planar surface.
- 15. (Original) The PEG kit as in claim 11, wherein at least one said recess disposed in said third planar surface is adapted to hold an introducer cannula.
- 16. (Original) The PEG kit as in claim 11, wherein said cover rests on a peripheral edge of said tray.
- 17. (Original) The PEG kit as in claim 11, wherein at least one said recess disposed in said first planar surface is adapted to retain at least a portion of a guide wire.
- 18. (Original) The PEG kit as in claim 11, wherein at least one said recess disposed in said second planar surface is adapted to retain an exterior tube retention device.
- 19. (Original) The PEG kit as in claim 11, wherein said container rests on at least a portion of said first planar surface.
- 20. (Currently Amended) The PEG kit as in claim 11, A percutaneous endoscopic gastrostomy (PEG) kit comprising:

a tray, said tray further comprising

a first planar surface comprising at least one recess disposed within the first planar surface.

a second planar surface comprising at least one recess disposed within the second planar surface, the second planar surface being offset from the first planar surface.

a third planar surface comprising at least one recess disposed within the third planar surface, the third planar surface being offset from the first planar surface

a container adapted to fit at least partially within the tray, the container adapted to rest upon at least one of the plurality of planar surfaces while leaving at least one said recess in said planar surface exposed, the container adapted to be reclosable and to retain accessory articles useful in performing a medical procedure; and

a cover adapted to be placed over the tray;

wherein each recess is adapted to hold at least one article useful in performing a medical procedure;

wherein at least one of said planar surfaces comprises at least one boss extending upwardly from the surface.

21. (Original) The PEG kit as in claim 20, wherein said boss extends upwardly from said second planar surface.